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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,004	11/14/2003	Stuart A. Kushon	8971-035-27	7816

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EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/712,004	<b>Applicant(s)</b> KUSHON ET AL.	
	<b>Examiner</b> David J. Venci	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on October 11, 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 1-15,33-51,53,54,56 and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-32,52,55 and 58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on November 14, 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/13/05; 05/05/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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## DETAILED ACTION

### *Election/Restrictions*

Examiner acknowledges Applicants' election of Group II, claims 16-32, 52, 55 and 58, in the reply filed on October 11, 2005. In addition, Examiner acknowledges Applicants' species election of the "AZO" compound.

Examiner acknowledges Applications' elections with traverse. However, Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement. Therefore, Applicants' election is treated as an election without traverse (MPEP § 818.03(a)). The restriction requirement is made FINAL.

Claims 1-15, 33-51, 53-54 and 56-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

### *Specification*

The disclosure is objected to because of the following informalities:

On pp. 13 and 33 of the specification, and claim 5, the depicted chemical structures of polyphenylene ethynylene containing intersecting vertical lines is indefinite. The information conveyed by said intersecting vertical lines is not clear. For example, whether the first set of vertical lines encompasses three or four ethynylene carbons is not clear. Appropriate correction is required.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-32, 52, 55 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, the recitation of the term "free" is indefinite. The identity of object(s) modified by "free" is not clear. Whether "free" modifies "biotin" and/or "binding sites" is not clear.

In claims 18-19, the recitation of "bioconjugate" is indefinite. The two or more objects belonging to the class "bioconjugate" are not clear.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The structural cooperative relationship between "the biotinylated bioconjugate" and "the complex" is not clear and appears omitted from claim 18. The recitation of the term "bound to" does not provide sufficient structural cooperative relationship between "the biotinylated bioconjugate" and "the complex" such that persons skilled in the art would not be apprised of the scope of this claim.

In claim 19, the recitation of "the polynucleotide *or peptide nucleic acid* sequence of the biotinylated bioconjugate" (emphasis added) results in a scope mismatch with "wherein the biotinylated bioconjugate comprises a polynucleotide sequence".

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In claim 19, the recitation of "a target analyte" is indefinite. Whether "a target analyte" is a required sensor limitation is not clear.

In claim 20, the recitation of "enzyme" is indefinite. Whether an "enzyme" is a required sensor limitation is not clear.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The structural cooperative relationships between "the complex", "a biotinylated bioconjugate", "a tether" and "the solid support" are not clear and appears omitted from claim 18.

In claim 31, the recitation of "biotin-binding protein" lacks antecedent basis and is indefinite. The structural implications of a hyphen between two nouns (i.e. "biotin" and "binding protein") is not clear.

In claims 52 and 58, the recitation of "the biotinylated bioconjugate" lacks antecedent basis.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16-18, 20 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Feltus *et al.*, 254 ANAL. BIOCHEM. 62 (1997).

Feltus *et al.* describe a sensor comprising a complex (see p. 62, col. 1, last line, "homogeneous system"; col. 2, lines 4-5, "heterogeneous competitive binding system") of biotinylated fluorescent polymer (see Title, "Aequorin-Biotin") and a biotin binding protein (see Abstract, "avidin immobilized on solid particles"), wherein the complex comprises free biotin (see p. 62, col. 2, line 3, "free biotin") binding sites (see Abstract, "avidin immobilized on solid particles").

With respect to claim 18, Feltus *et al.* describe a sensor further comprising a biotinylated (see p. 64, col. 2, last paragraph, "biotin effectively competes for the binding sites on the avidin particles") bioconjugate comprising a polypeptide (see p. 64, col. 2, last paragraph, "avidin particles").

With respect to claim 20, Feltus *et al.* describe a quencher (see p. 63, col. 1, *Reagents*, "Sphero-avidin magnetic particles"). The recitation "wherein the quencher is capable of amplified super-quenching of the

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fluorescent polymer" provides no further limiting structural definition to said "quencher" or said "sensor", and is not afforded patentable weight in this instance.

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Claims 16-18, 20-22 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Adamczyk *et al.*, 3 ORG. LETT. 1797 (2001).

Adamczyk *et al.* describe a sensor comprising a complex of biotinylated fluorescent polymer and a biotin binding protein, wherein the complex comprises free biotin binding sites (see Abstract, cartoon drawing, complex to the right of arrow).

With respect to claim 17, Adamczyk *et al.* describe a sensor comprising a solid support (see p. 1799, col. 1, "microplate luminometer").

With respect to claim 18, Adamczyk *et al.* describe a sensor further comprising a biotinylated bioconjugate comprising a polypeptide (see Fig. 5, "biotinylated BSA").

With respect to claim 31, Adamczyk *et al.* describe a sensor wherein a biotinylated fluorescent protein (see p. 1800, col. 1, "biotinylated aequorin") forms a complex with a biotinylated fluorescent polymer (see Fig. 5, "biotinylated BSA", noting inherency of  $\pi$  bond fluorescence) and a biotin-binding protein (see Fig. 5, "QSY-7-avidin").

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Claims 16-20, 22-24, 52 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Zarling *et al.* (US 6,537,829).

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Zarling *et al.* describe a sensor comprising a complex of biotinylated fluorescent polymer (see col. 50, line 41, “[b]iotinylated polynucleotides”) and a biotin binding protein (see col. 50, line 43, “streptavidin-coated up-converting phosphors”), wherein the complex comprises free biotin binding sites (see col. 54, line 57, “[u]nbound avidin-conjugates”).

With respect to claims 20 and 52, Zarling *et al.* describe a quencher (see col. 50, line 43, “streptavidin-coated up-converting phosphors”). The recitation “wherein the quencher is capable of amplified super-quenching of the fluorescent polymer” provides no further limiting structural definition to said “quencher” or said “sensor”, and is not afforded patentable weight in this instance.

With respect to claim 55, Zarling *et al.* describe a silica solid support (see col. 16, Table I).



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***Response to Arguments***

In prior Office Action, Examiner requested clarification of symbology in the specification and claims. Specifically, on pp. 13 and 33 of the specification, and claim 5, the depicted chemical structures of polyphenylene ethynylene contain intersecting vertical lines and recite the text "1/4" and "3/4". Applicants' clarification with respect to the text "1/4" and "3/4" is sufficient. Applicants' clarification with respect to the intersecting vertical lines is not sufficient for the reasons set forth *supra*.

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**Conclusion**

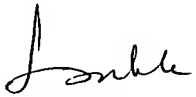
No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci  
Examiner  
Art Unit 1641

djv

  
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01/20/06